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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/761,150	01/20/2004	Jose Manuel Andreu Morales	1379-1-022	1559

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KLAUBER & JACKSON
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EXAMINER

FETTEROLF, BRANDON J

ART UNIT	PAPER NUMBER
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1642

MAIL DATE	DELIVERY MODE
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11/15/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<p align="center">Advisory Action Before the Filing of an Appeal Brief</p>	Application No. 10/761,150	Applicant(s) ANDREU MORALES ET AL.	
	Examiner Brandon J. Fetterolf, PhD	Art Unit 1642	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 12 October 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 5 months from the mailing date of the final rejection.
 b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
 (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
 (b) ☒ They raise the issue of new matter (see NOTE below);
 (c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
 5. ☐ Applicant's reply has overcome the following rejection(s): _____.
 6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
 7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
 The status of the claim(s) is (or will be) as follows:
 Claim(s) allowed: _____.
 Claim(s) objected to: _____.
 Claim(s) rejected: 1,2,4,5,7,8,10,11 and 13-18.
 Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☒ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
 10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
 12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____.
 13. ☐ Other: _____.

DETAILED ACTION

Response to the Amendment

The Amendment filed on 10/12/2007 in response to the previous Final Office Action (5/11/2007) is acknowledged, but has not been entered. The amendment has not been entered because they raise issues that would require further consideration, with regards to 112, 1st paragraph and 2nd paragraph and search, with regards to 102 and 103. For example, the amended claims recite that the “method is based on the combination of a target and a probe, wherein the target microtubules assembled in vitro ...” However, it is unclear what the target is since the claims recite “a target” and “the target microtubules”. Moreover, the claims have been amended to recite “identifying the test substance as said substance substitutive of paclitaxel”. However, “said substance substitutive of paclitaxel” has not been previously considered or searched.

Claims 1-2, 4-5, 7-8, 10-11 and 13-18 are currently pending and under consideration.

The Declaration under 37 CFR 1.132 filed by the inventors Andreu and Diaz to overcome the rejection of Claims 1-2, 4-5, 7-8, 10-11 and 13-18 under 35 U.S.C. 102(b) as being anticipated by Diaz et al. (J. Biol. Chem. 2000; 275: 26265-26276, *IDS*) has not been considered since the affidavit was filed after a final action and failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116 (e).

Priority:

The Examiner acknowledges and appreciates Applicants submission of the PCT priority document and an English Translation of the same. However, the Examiner recognizes that a translation of the certified copy of the Spanish Application Serial No. 200101710 submitted on 6/23/2004, which Applicants claim priority to under U.S.C. 119(a)-(d) has not been received. As stated in the prior office action, a certified copy of the international application (and an English translation) of the international application may be required by the examiner to perfect the claim for benefit under 35 U.S.C. 120 and 365(c) if the international application did not originate in the United States and such is necessary, for example, where an intervening reference is found and applied in a rejection of one or more claims, see MPEP 1895.01 [R5]. (emphasis added) As such, the

Art Unit: 1642

Examiner has established a priority date of **5/31/2002** consistent with the PCT Application, PCT/ES02/00262. Thus, while the Examiner concedes that Claims 1-2, 4-5, 7-8, 10-11 and 13-18 are no longer rejected under 35 U.S.C. 102(b) as being anticipated by Andreu et al. (Biochemistry 2001; 40: 11975-11984, *IDS*), the Examiner recognizes claims 1-2, 4-5, 7-8, 10-11 and 13-18 are rejected under 35 U.S.C. 102(a) as being anticipated by Andreu et al. (Biochemistry 2001; 40: 11975-11984, *IDS*) since the authors of the Andreu et al. reference is different from the inventive entity of the instant Application.

Information Disclosure Statement

The Information Disclosure Statement filed on 5/12/2005 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner. A signed copy of the IDS is attached hereto.

Rejections Maintained:

As Applicant's arguments appear to be solely drawn to the 1.132 Declaration filed after the final rejection, which has not been considered and the currently amended claims, which have not been entered, the following rejections are maintained:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 4-5, 7-8, 10-11 and 13-18 remain rejected under 35 U.S.C. 102(b) as being anticipated by Diaz et al. (J. Biol. Chem. 2000; 275: 26265-26276, *IDS*).

(Note: Due to the indefiniteness of the phrase "displacement equilibrium curve" in claim 1, see below, the claim will be interpreted as determining a displacement curve.)

Diaz et al. teach a method of providing a homogenous test for the detection of an antitumor substance in the paclitaxel binding site of microtubules, wherein said method is based on the

Art Unit: 1642

combination of a target and a probe and comprises the following steps: adding a test substance or test substances to a solution of a target consisting of microtubules and a fluorescent probe bound to the target; determining a displacement curve of the probe from the target by the test substance, wherein the displacement is determined by measuring the the variation of the fluorescence intensity of the probe; and identifying a biomimetic compound of paclitaxel, wherein the biomimetic compound is identified by a drop in anisotropy of the fluorescence of the probe (page 26265, 2nd column, *Kinetics of Binding and Dissociation of Fluorescent Taxoids to Microtubules*, page 26267, 1st column and Figure 1). With regards to the microtubules, the reference teaches cross-linked microtubules assembled in vitro in GAB and preserved with glutaraldehyde, wherein the cross-linked microtubules were found to be stable against low temperatures and dilution (page 26266, 2nd column, Preparation of Cross-linked Microtubules). With regards to the probe, Diaz et al. teach two fluorescence taxoids, 7-O-[N-(4'-fluoresceincarbonyl)-L-alanyl]Taxol (Flutax-1) and 7-O-[N-(2,7-difluoro-4'-fluoresceincarbonyl)-L-alanyl]Taxol (Flutax-2) which bind to microtubules with high affinity (abstract). With regards to antitumor substance, e.g., a test substance, which binds to the paclitaxel binding site of microtubules, the reference teaches that docetaxel was used for displacing the fluorescent probes due to it ability to bind to the Taxol binding site and larger solubility (page 26267, 1st column, paragraph bridging page 26266). Moreover, the reference teaches that the fluorescence anisotropy of the samples was measured using a Spex spectrofluorometer plate reader (page 26266, 2nd column, 4th full paragraph). Thus, while Diaz et al. do not explicitly teach the preambles recited in claims 13-18 which utilize the steps of the method of claim 1, a preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. (emphasis added) See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). In addition, although Diaz et al. do not explicitly teach that the microtubules are conserved indefinitely in liquid nitrogen following dialysis against a conservation and cryopreservation buffer, the claimed limitation does not appear to result in a manipulative difference between the prior art microtubules stabilized by means of cross-linking. In the instant situation, the office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same

Art Unit: 1642

material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See *In re Best* 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2, 4-5, 7-8, 10-11 and 13-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "displacement equilibrium curve" in claim 1 is a relative term which renders the claim indefinite. The phrase "displacement equilibrium curve" is not defined by the claim and the specification does not provide a standard for ascertaining the requisite degree which is encompassed by the phrase "displacement equilibrium curve". Thus, one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. For prior art purposes, the claims will be interpreted as determining a displacement curve.

Claim 1 recites the limitation "the biomimetic compound" in step "2" of claim 1. There is insufficient antecedent basis for this limitation in the preamble or steps "1" and "2" of claim 1.

Claim 1 recites in step "2" an active step of determining the displacement equilibrium curve of the probe from the target by any test substance, wherein the biomimetic compound is identified by measuring a drop in anisotropy at varying test substance concentrations, or the variation of fluorescence intensity of the probe, or the resonance energy transfer of the probe to a suitable acceptor; and further, recites in step "3" an active step of identifying a biomimetic compound of paclitaxel, wherein the biomimetic compound is identified by a drop in anisotropy of the fluorescence of the probe or by means of a drop in resonance energy transfer to the probe bound to a ligand. Thus, claim 1 recites two active steps of identification, which renders the claim indefinite. For prior art purposes, the claims will be interpreted as using any of the identification techniques recited in steps "2" or "3".

Art Unit: 1642

Claims 1-2, 4-5, 7-8, 10-11 and 13-18 are further rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: a drop in anisotropy and what is being measured in step “2” of the claimed method. For example, Merriam-Webster defines anisotropy as exhibiting properties with different values when measured in different directions. Thus, while in this case the value could be presented as the concentrations, the claims do not appear to define what the “property” is. For prior art purposes, the claims will be interpreted as measuring the drop in anisotropy in the variation of fluorescence intensity of the probe.

Claims 1-2, 4-5, 7-8, 10-11 and 13-18 are further rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: a correlation between the determining step and the identification step. In the instant case, it is unclear how determining a displacement equilibrium curve can be used to identify a biomimetic compound of paclitaxel.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2, 4-5, 7-8, 10-11 and 13-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. THIS IS A NEW MATTER REJECTION.

Claim 1 has been amended to recite “determining the displacement equilibrium curve of the probe from the target by any test substance.” Applicants assert that support for the limitation “determining the displacement equilibrium curve” can be found in paragraphs [0013], [0014] and [0026], and Figure 2 of the specification (see Remarks, page 7). However, a careful review of the originally filed specification and claims, as well as the paragraphs and figures pointed to by Applicants, does not appear to lend support for this limitation. For example, paragraphs [0013] and [0014] describe substance which can be tested in the instant method, as well as, how to detect a

Art Unit: 1642

competitor substance, e.g., by drop in fluorescence anisotropy of the probe (referenced ligand). However, these paragraphs do not appear to describe determining a displacement equilibrium curve. In addition, paragraph [0026] describes a fluorescence micrograph of a typical reaction mixture used in the invention and Figure 2 describes the fluorescence anisotropy of multiple solutions of 50nM Flutax-2 and binding sites of 50 nM microtubules with various concentrations of competitors (see paragraph 0027 of the specification). Yet, paragraph [0026] and Figure 2 do not appear to lend support for the limitation "determining the displacement equilibrium curve". As such, Applicant is required to cancel the new matter in the response to this Office Action. Alternatively, applicant is invited to provide sufficient written support for the "limitation" indicated above. See MPEP 714.02 and 2163.06

Claims 1-2, 4-5, 7-8, 10-11 and 13-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether undue experimentation is required are summarized in *re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988). The court in *Wands* states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.'" (*Wands*, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (*Wands*, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the nature of the invention, (2) the relative skill of those in the art, (3) the breadth of the claims, (4) the amount or direction or guidance presented, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the state of the prior art, and (8) the predictability or unpredictability of the art.

Although the quantity of experimentation alone is not dispositive in a determination of whether the required experimentation is undue, this factor does play a central role. For example, a

Art Unit: 1642

very limited quantity of experimentation may be undue in a fledgling art that is unpredictable where no guidance or working examples are provided in the specification and prior art, whereas the same amount of experimentation may not be undue when viewed in light of some guidance or a working example or the experimentation required is in a predictable established art. Conversely, a large quantity of experimentation would require a correspondingly greater quantum of guidance, predictability and skill in the art to overcome classification as undue experimentation. In *Wands*, the determination that undue experimentation was not required to make the claimed invention was based primarily on the nature of the art, and the probability that the required experimentation would result in successfully obtaining the claimed invention. (*Wands*, 8 USPQ2d 1406) Thus, a combination of factors which, when viewed together, would provide an artisan of ordinary skill in the art with an expectation of successfully obtaining the claimed invention with additional experimentation would preclude the classification of that experimentation as undue. A combination of *Wands* factors, which provide a very low likelihood of successfully obtaining the claimed invention with additional experimentation, however, would render the additional experimentation undue.

The nature of the invention

The claims are drawn to an in vitro test for determining a compound which can act as a substitute for paclitaxel in the paclitaxel binding site of microtubules.

Level of skill in the art

The level of skill in the art is deemed to be high, generally that of a PhD.

The breadth of the claims

Applicants broadly claim a method of providing a homogeneous test for the detection of any antitumor substance substitutive of paclitaxel in the paclitaxel binding site of microtubules comprising adding a test substance or test substances to a solution of a target consisting of microtubules and a fluorescent probe bound to the target, determining the displacement equilibrium curve of the probe from the target by any test substance, wherein the biomimetic compound is identified by measuring the drop in anisotropy at varying test substance concentrations, or the

Art Unit: 1642

variation of fluorescence intensity of the probe, or the resonance energy transfer of the probe to a suitable acceptor, and identifying a biomimetic compound of paclitaxel, wherein the biomimetic compound is identified by a drop in anisotropy of the fluorescence of the probe or by means of the drop in resonance energy transfer to the probe bound to a ligand. Thus, the claims encompass three active steps of contacting, determining, and identifying a biomimetic compound of paclitaxel.

Guidance in the specification and Working Examples

The specification teaches that the objection of the present method is based on the combination of the target, which consists of microtubules assembled in vitro and stabilized by means of chemical cross linking, and the probe which consists of fluoresceinated derivatives of paclitaxel, which are specifically bound to microtubules (paragraph 0012). In particular, the specification teaches that when the probe is bound to the target it possesses a much greater fluorescence anisotropy value than that of the free probe, wherein the displacement of the probe with the target with any competitor substance can be detected by means of the drop in fluorescence anisotropy of the probe or by the drop in the resonance energy transfer (RET) or by the change in fluorescence intensity of the probe (paragraph 0014). The specification further provides validation of the probe to target by measuring the fluorescence anisotropy (page 7) and energy transfer (page 8). Thus, while the specification clearly teaches determining the displacement of the probe by measuring the drop in fluorescence anisotropy of the probe or by the drop in the resonance energy transfer (RET) or by the change in fluorescence intensity of the probe (paragraph 0014), the specification does not appear to describe what a displacement equilibrium curve is or how to determine a displacement equilibrium curve.

Quantity of experimentation

The quantity of experimentation is extremely large given the fact that the specification, as well as the prior art, does not appear to teach what a displacement equilibrium curve is or how to determine one.

Conclusion

Thus, given the lack of guidance provided in the specification for determining a displacement equilibrium curve, it is the position of the examiner that it would require undue experimentation for one of skill in the art to perform the method of the claim as written.

New Rejections Necessitated by Applicants Submission of the English Translation of the PCT priority document:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-2, 4-5, 7-8, 10-11 and 13-18 remain rejected under 35 U.S.C. 102(b) as being anticipated by Andreu et al. (Biochemistry 2001; 40: 11975-11984, *IDS*).

(Note: Due to the indefiniteness of the phrase "displacement equilibrium curve" in claim 1, the claim will be interpreted as determining a displacement curve.)

Andrue et al. teach a method of providing a homogenous test for the detection of an antitumor substance in the paclitaxel binding site of microtubules, wherein said method is based on the combination of a target and a probe and comprises the following steps: adding a test substance or test substances to a solution of a target consisting of microtubules and a fluorescent probe bound to the target; determining the displacement curve of the probe from the target by the test substance, wherein the displacement is determined by measuring the drop in anisotropy via the variation of the fluorescence intensity of the probe and the resonance energy transfer to the probe bound to a suitable acceptor; and identifying a biomimetic compound of paclitaxel, wherein the biomimetic compound is identified by a drop in anisotropy of the fluorescence of the probe (entire document, specifically, page 11976, 2nd column, 1st full paragraph and page 11979, 2nd column, *Competitive Fluorescent Assay of Ligand Binding to Microtubules Measures the Binding of Taxol and Baccatin III*, and page 11980, Figure 4). With regards to the microtubules, the reference teaches cross-linked microtubules

Art Unit: 1642

assembled in vitro and indefinitely conserved by means of dialysis against a conservation and cryopreservation buffer followed by drop-freezing into liquid nitrogen (page 11976, 1st Column, *Cross-Linked Microtubule* and page 11982, 2nd column, 1st full paragraph). With regards to the probe, Andrue et al. teach that the probe includes 7-O-[N-(2,7-difluoro-4'-fluoresceincarbonyl)-L-alanyl]Taxol (abstract). With regards to antitumor substance, e.g., a test substance, which binds to the paclitaxel binding site of microtubules, the reference teaches that docetaxel and baccatin III recognizes the Taxol binding site of microtubules (page 11979, 2nd column, *Competitive Fluorescent Assay of Ligand Binding to Microtubules Measures the Binding of Taxol and Baccatin III*). Moreover, the reference teaches that the fluorescence anisotropy of the samples was screened in 96-well plates using a microplate reader (page 11979, 2nd column, 1st full paragraph). Andrue et al. further teach that the method can be used to screen for Taxol mimetics such as evaluating the binding affinity of newly designed compounds of the Taxol, epothilone, eleutherobin and discodermolide families, as well as measuring the active Taxol-like contents of natural sources (page 11981, 2nd column, *Potential Uses of Fluorescence Anisotropy Multiwell Plate Assay in Comparison with Other Methods To Screen for Taxol Mimetics*). Thus, while Diaz et al. do not explicitly teach the preambles recited in claims 13-18 comprising the steps of the method of claim 1, a preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. (emphasis added) See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Therefore, NO claim is allowed

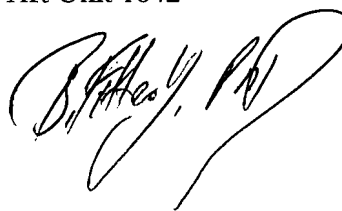
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J. Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached on Monday through Friday from 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1642

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brandon J Fetterolf, PhD
Patent Examiner
Art Unit 1642

A handwritten signature in black ink, appearing to read 'B. Fetterolf, PhD', with a large, stylized flourish extending from the end.

BF